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Docket No. 0002.12

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

John Patton

Examiner: David LUKTON

Serial No.: 09/577,264

Art Unit: 1653

Filed: May 22, 2000

Title: **PULMONARY DELIVERY OF ACTIVE
FRAGMENTS OF PARATHYROID HORMONE**

RESPONSE TO RESTRICTION AND ELECTION OF SPECIES REQUIREMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Sir:

In response to the Restriction and Election of Species Requirement dated May 4, 2005, reconsideration of this application in view of the following remarks is respectfully requested. The period for response has been extended four months to October 4, 2005 by the accompanying petition.

In the Restriction and Election of Species Requirement, the Office has required restriction under 35 U.S.C. § 121 between the following groups of claims:

- I. Claims 20-31, drawn to a device that contains a composition, wherein the composition comprises a PTH fragment, a bulking agent, and a propellant;
- II. Claims 32-55, drawn to a device that contains a composition, wherein the composition comprises a PTH fragment and a propellant, but the composition lacks a penetration enhancer;

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III. Claims 56, 57, and 59, drawn to a method for treating a host by administering a composition which comprises a PTH fragment, a bulking agent, and a propellant; and

IV. Claim 58, drawn to a method for treating a host by administering a composition which comprises a PTH fragment and a propellant, and wherein the composition lacks a penetration enhancer.

In response, Applicant hereby elects Group III, claims 56 and 57, with traverse.¹

Additionally, the Office has required an election of species "to which the claims shall be restricted if no generic claim is finally held to be allowable." In particular, the Office has required an election of:

- a) a specific fragment of PTH, e.g., a peptide which consists of the 34 N-terminal amino acids of SEQ ID NO: 1;
- b) the composition is one of the following: (i) in the form of a powder and no liquid is present, (ii) mixture of a solid and a liquid in which most or all of the solid is insoluble, or (iii) a homogeneous solution which is obtained by dissolving a solid composition into a liquid; and
- c) a specific, fully defined composition in which 100% of the ingredients are accounted for.

As the species, for searching purposes, Applicant elects a) the 34 N-terminal amino acids of SEQ ID NO: 1; b) dry powder form; and c) sucrose bulking agent and tetrafluoroethane (HFC-134a) propellant. Applicants note that this election of species is made for searching purposes and does not affect the scope of the claims. With regard to the elected claims of Group III, at least claims 56 and 57 read on the elected invention.

¹ Although the Restriction Requirement indicates that Group III includes claims 56, 57, and 59, Applicant believes that the Examiner may have intended to include claim 59 in Group IV. In this regard, claim 59 depends on claim 58 of Group IV.

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Applicant traverses the Restriction and Election of Species Requirement on the grounds that the Office has not shown that there would be a serious burden to examine all of the pending claims together. In fact, the Office has failed to assert that any such burden exists. Accordingly, Applicant respectfully submits that the Restriction and Election of Species Requirement is improper, and request that it be withdrawn.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 500348.

Respectfully submitted,
Nektar Therapeutics

Date: 10/04/05

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